

REMARKS

The Drawings have been replaced with formal Drawings. Claims 28 and 35-36 have been amended. Thus, claims 1 - 36 remain pending in this application. No new matter has been added. In view of the above amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

The Examiner has objected to the Drawings. As the Examiner will ascertain, the Drawings have been replaced. Thus, Applicants respectfully request that the Examiner withdraw the objection to the Drawings.

Claims 35 and 36 have been rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter when Applicants regard as the invention. Claims 35 and 36 have been amended to depend from independent method claim 28. Thus, Applicants respectfully request that the Examiner withdraw the rejections of these claims.

Claims 1-2, 4, 5, 15, 28-30 and 32-35 have been rejected under 35 U.S.C. § 102(a) as anticipated by U.S. Patent Publication No. 2003/0069592 to Adams et al. ("Adams").

Claim 1 recites an apparatus for deployment of a hemostatic clip comprising "a handle assembly" and "a shaft connected to a distal portion of the handle assembly" in combination with "a clip assembly releasably coupled to a distal portion of the shaft, the clip assembly including clip arms and a capsule cooperating with the clip arms to provide a first user feedback indicating a decision configuration of the clip assembly" and "*a control wire including a ball connector, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft.*"

In contrast, Adams shows a medical device consisting of a handle, a sheath 1206 extending distally therefrom and a clip 1201 disposed at a distal end of the sheath 1206. A control wire 1207 extending within the sheath 1206 is connected at a proximal end to the handle and at a distal end to the clip 1201. As the control wire 1207 is drawn proximally through the sheath 1206, a ball 1202 at a distal end of the control wire 1207 pulls the clip 1201 proximally through an outer sleeve 1204, which is connected to the distal end of the sheath 1206. The clip 1201 is locked into place within the outer sleeve 1204 when socket tabs 1203 at a proximal end of the clip 1201 fit into cut-outs 1205 in the outer sleeve 1204. Simultaneously, the ball 1202 is released from the clip 1201. The outer sleeve 1204 is then disengaged from the sheath 1206 when the sheath 1206 is drawn proximally.

In support of the rejection of claim 1, the Examiner states that Adams discloses

a clip assembly 101 releaseable coupled to the distal portion of the shaft, the clip having arms 102 and 103 and a capsule 111 which is capable for providing a first user feedback indicating the clip configuration; and a control wire 1207 including a ball connector 1202, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft (see Figs 12a and 12b).

(12/3/04 *Office Action*, p. 3). It is respectfully submitted that the Examiner is combining two embodiments of the device, whereas Adams does not disclose or suggest this combination. For example, the embodiment including the capsule 111 and clip assembly 101 utilizes a control wire 108 with a j-hook 107 attachment to the clip 101. (*Adams*, ¶ [0077]; Fig. 1). The embodiment which utilizes the control wire 1207 with ball connector 1202 is described as an “alternative to the j-hook type frangible link.” (*Id.* ¶ [0084]; Figs. 12a, 12b). That is, the ball connector 1202 would not work if substituted for the j-hook 107, and vice-versa. Thus, it is respectfully submitted that the features of the device described with regard to the clip 101 and the capsule 111 are separate, distinct from and structurally incompatible with those features of the control wire 1207 and ball connector 1202.

Furthermore, Adams fails to disclose or suggest “a control wire including a ball connector, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft.” That is, separating the ball connector 1202 from the clip 1201 would not provide the user with feedback which indicates that the outer sleeve 1204 has separated from the sheath 1206. Adams states, “when the sheath 1206 is pulled back through the working channel (not shown) of the endoscope (not shown), the outer sleeve 1204 will release with the clip 1201.” (*Adams*, ¶ [0084]). Thus, the user notices that the outer sleeve 1204 (and clip 1201) has been released only when the user pulls the sheath 1206 proximally through an endoscope and not when the ball connector 1202 is separated from the clip 1201. Therefore, it is respectfully submitted that Adams neither discloses nor suggests “a control wire including a ball connector, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft,” as recited in claim 1.

Applicants respectfully request that the rejection of claim 1 be withdrawn. Because claims 2, 4, 5 and 15 depend from, and, therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable.

Claim 28 recites a method for hemostatic clipping comprising “inserting a shaft of a clipping device through a working lumen of an endoscope, wherein the shaft extends to a distal clipping assembly of the clipping device including a plurality of clip arms and wherein a control wire extends through the shaft from the clipping assembly to a handle coupled to a proximal end of the shaft” and “manipulating the handle assembly to move a control wire within the shaft to move the clip arms between an open and a closed configuration” in combination with “generating, *by the clipping device*, a first user feedback indicating a decision configuration of the apparatus” and “generating, *by the clipping device*, a second user feedback indicating

separation of the clipping assembly from the shaft.”

Adams states that any feedback that the user receives regarding operation of the device is due to optical components of the endoscope which houses the device. That is, “[t]he success or failure of the application of pressure can be reviewed through the optical components provided separately in the endoscope.” (*Adams*, ¶ [0102]). Thus, it is respectfully submitted that Adams neither discloses nor suggests “generating, *by the clipping device*, a first user feedback indicating a decision configuration of the apparatus” and “generating, *by the clipping device*, a second user feedback indicating separation of the clipping assembly from the shaft,” as recited in claim 28. Because claims 29-30 and 32-35 depend from, and, therefore include all of the limitations of claim 28, it is respectfully submitted that these claims are allowable for the same reasons as stated above.

Claims 6-9, 12-14, 16 and 19-27 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Adams in view of U.S. Patent No. 4,733,664 to Kirsch et al. (“Kirsch”).

With regard to claims 6-9, 12-14 and 16, Applicants respectfully submit that Kirsch does not cure the above-described deficiencies of Adams. That is, Kirsch does not disclose or suggest “a control wire including a ball connector, the control wire extending from the handle assembly and coupled to the clip assembly by the ball connector to maintain the clip assembly coupled to the shaft, wherein the ball connector is detachable from the clip assembly to provide a second user feedback indicating separation of the clip assembly from the shaft,” as recited in claim 1, or, “generating, by the clipping device, a first user feedback indicating a decision configuration of the apparatus” and “generating, by the clipping device, a second user feedback indicating separation of the clipping assembly from the shaft,” as recited in claim 28. Thus, because claims 6-9, 12-14 and 16 depend from, and, therefore include all of the limitations of claim 1, it is respectfully submitted that these claims are allowable.

Claim 19 recites a clip deployment apparatus insertable to locations within a body

through an endoscope, the apparatus comprising “an elongated member extending from a proximal end to a distal end” and “a control wire extending from the proximal end of the elongated member to the distal end thereof” and “a bushing coupled to the distal end of the elongated member” in combination with “a capsule releasably connected to the bushing” and “clip arms slidable within the capsule between a distal open configuration and a proximal closed configuration” and “a tension member slidable with the clip arms, the tension member biasing the clip arms toward the open configuration” and “a yoke slidable within the capsule, a first end of the yoke being releasably connected to the tension member and a second end of the yoke being connected to the control wire, wherein distal movement of the control wire slides the clip arms into the open configuration, and proximal movement of the control wire slides the clip arms into the closed configuration.”

Initially, it should be noted that Adams does not disclose or suggest “a tension member slidable with the clip arms, the tension member biasing the clip arms toward the open configuration” and “a yoke slidable within the capsule, a first end of the yoke being releasably connected to the tension member and a second end of the yoke being connected to the control wire, wherein distal movement of the control wire slides the clip arms into the open configuration, and proximal movement of the control wire slides the clip arms into the closed configuration.” The Examiner has stated that Adams “is silent with respect to a tension member releasably connected to the yoke and to the clip arms.” (12/3/04 *Office Action*, p. 5). Applicants assume that the Examiner means that Adams does not disclose a tension member or a yoke, as recited because the yoke is recited as releasably connected to a tension member which is not disclosed in Adams. Furthermore, Applicants have been unable to locate in Adams either “a tension member” or “a yoke” as recited in claim 19.

Applicants respectfully submit that Kirsch does not cure the above-mentioned deficiencies of Adams. That is, Kirsch fails to disclose or suggest “a tension member slidable with the clip arms, the tension member biasing the clip arms toward the open configuration” as recited in claim 19. As shown in Figs. 2-4 of Kirsch, a clip consists of arms 10 and 11 at a distal

end thereof and a neck 21 connected to a tang 19. As the tang 19 is pulled proximally, an applicator tool acts as a stop, closes the arms 10 and 11 on tissue therebetween and fractures the clip at the neck 21. The arms 10 and 11 have an initial open state (at rest) and a closed state created by proximal movement of the tang 19. The arms 10 and 11 are not biased to the open state. Thus, it is respectfully submitted that Kirsch fails to disclose or suggest “a tension member slidable with the clip arms, the tension member biasing the clip arms toward the open configuration,” as recited in claim 19.

Therefore, Applicants respectfully submit that neither Adams nor Kirsch, either alone or in combination, discloses or suggests “a tension member slidable with the clip arms, the tension member biasing the clip arms toward the open configuration,” as recited in claim 19. Because claims 20-27 depend from, and, therefore include all of the limitations of claim 19, it is respectfully submitted that these claims are allowable for the reasons discussed above.

Applicants respectfully submit that claim 31, which depends from, and, therefore includes all of the limitations of claim 28, is allowable for the reasons discussed above with regard to claim 28.

Claims 3, 10, 11, 17 and 18 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Adams in view of U.S. Patent No. 6,814,742 to Kimura et al. (“Kimura”).

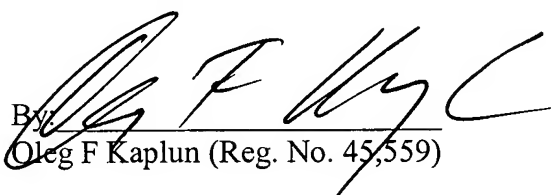
It is respectfully submitted that Kimura does not cure the above-noted deficiencies of Adams. Thus, Applicants respectfully submit that claims 3, 10, 11, 17 and 18, which depend from, and, therefore include all of the limitations of claim 1, are allowable for the reasons stated above with regard to claim 1.

CONCLUSION

It is therefore respectfully submitted that all of the presently pending claims are allowable. A prompt and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at (212) 619-6000, ext. 203 to discuss any matter concerning this application.

Respectfully submitted,

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IN THE DRAWINGS

Please substitute Figs. 1-29 with new Figs. 1-29 enclosed herewith.